## REMARKS

Favorable consideration of the subject application is respectfully requested in view of the following remarks. This Amendment and Reply is being filed within three months following the shortened statutory period for response and is accompanied by a Petition for a Three Month Extension of Time and the requisite fee. This response is therefore timely filed.

Claims 1, 2, 11, 13-28 and 30-33 are pending in this application, with claims 1, 24, 27 and 30 being in independent format.

## Claim Rejections under 35 USC §102(b) – maintained

The rejection of claims 1, 11 and 14 as being anticipated over *Antoniades et al.* was maintained for the reasons set forth in previous Office actions. Applicant traverses this rejection for the reasons set forth in Applicant's responses to the same rejection stated in previous Office actions and for the additional reasons stated below. Applicant awaits a final rejection so these issues may be resolved on appeal.

*Antoniades et al.* is directed to healing an external wound in a mammal, *e.g.*, a human patient, by applying to the wound an effective amount of a composition that includes a combination of purified PDGF and purified IL-1, or purified IGF-1 and purified IL-1. *See*, Col. 2, lines 10-14. The compositions of *Antoniades et al.* are prepared as molar concentrations, with the active component (PDGF and IL-1 or IGF-1 and IL-1) dissolved in a pharmaceutically acceptable carrier substance, e.g. commercially available inert gels, or membranes, or liquids. *See*, Col. 2, lines 26-29.

Applicant's independent claim 1 recites preparations comprising *specific homeopathic potencies* of IGF-1 suitable for oral administration, wherein the purified IGF-1 has a homeopathic potency selected from the group consisting of: 6X, 6C, 15X, 12C, 30C, 100C, 200C and 1M (1000C). Homeopathic potencies, as evidenced by applicant's specification and the materials of record in the prosecution of this application relating to homeopathy and homeopathic preparations, have a long history and are well known and well established in the art. The meaning and significance of a *homeopathic preparation*, and the *specific homeopathic potencies* recited in the

pending claims, contrasted with preparations made using molar concentrations of materials, is well known to those having ordinary skill in the art of homeopathy. The terms *homeopathic preparation* and *homeopathic potency*, and the specific homeopathic potencies claimed, have precise meanings to those having ordinary skill in the art of homeopathy. The meaning and significance of homeopathic preparations and potencies do not relate to molar concentrations and pharmaceutically prepared compositions but, rather, to specialized and standardized techniques involving both serial dilutions and serial succussions. Additional methodologies for preparing homeopathic preparations are also being developed and tested. Homeopathic preparations are generally highly dilute preparations, but it is the preparatory process, and not merely the highly dilute nature of the preparation, that renders a preparation a ***homeopathic potency***. Preparation of homeopathic potencies is described, for example, in VITHOULKAS, George; "The Science of Homeopathy," pp. 157-167 (1980 Grove Press, New York); LEROY, Debra; "Potencies," printed 10/16/2000; BELLAVITE, Paolo M.D., et al.; "Homeopathy – A Frontier in Medical Science," pp. 11-12 (1995 North Atlantic Books, California). These references were listed in the Evidence Appendix accompanying the applicant's Appeal Brief, and copies of the references were provided.

There is no teaching or suggestion whatsoever in *Antoniades et al.* that the compositions are homeopathic preparations or homeopathic potencies. There is no description, either expressly or inherently, of homeopathic potencies, or of serial dilutions and serial succussions or other homeopathic techniques. No homeopathic nomenclature is used. There is no mention of the possibility or desirability of homeopathic preparations, as specified in applicants' claims.

The Examiner states that in the absence of a disclosure of a particular starting concentration of IGF-1 in the independent claim, it is anticipated that the (molar) "concentration" of applicants' claimed preparations comprising a homeopathic potency of purified IGF-1 may be disclosed by IGF-1 concentrations described in Antoniades et al. Applicant submits that this is irrelevant. The Examiner is not viewing the claim language from the perspective of one having ordinary skill in the art of homeopathy. Applicants reiterate that the molar concentration of homeopathic preparations is not an important or characterizing feature of the homeopathic preparations. Rather, it is the energetic properties imparted to the preparations as a result of the

specialized and standardized techniques of preparing homeopathic potencies, involving both serial dilutions and serial successions, that characterize and define homeopathic potencies. Even if the molar concentrations of applicants' homeopathic preparations were substantially the same as those disclosed by *Antoniades et al.* (which applicant doesn't concede), a homeopathic preparation is different and distinct from a pharmaceutically prepared composition and there is no anticipation.

The Examiner appears to suggest a product-by-process analysis - but applicant's claims are not product-by-process claims. They are claims directed to homeopathic preparations and homeopathic potencies, which terms are well known to those having ordinary skill in the art and science of homeopathy. Just as a claim to a 0.5 molar solution of IGF-1 wouldn't require a product-by-process analysis, even though there is a standard preparation process for molar solutions, a claim to specific homeopathic potencies of IGF-1 shouldn't invoke a product-by-process analysis, even though there is a standard preparation for homeopathic potencies.

There is a body of literature hundreds of years old relating to homeopathic preparations and treatments. Homeopathy is practiced widely in the U.S., in Europe, and elsewhere. The art and science of homeopathy and homeopathic medicine is a different discipline from the science of allopathic medicine and pharmaceutically prepared compositions. Homeopathic preparations are recognized to be different from pharmaceutical preparations, are sold through different channels, and are regulated entirely differently from pharmaceutical preparations.

The Examiner argues that because there may be overlapping concentrations of IGF-1 in the cited prior art and the homeopathic preparations recited in applicant's claims, that the burden has shifted to applicant to provide evidence that the claimed compositions are different from those in the prior art. Applicant's position is that the claimed compositions are different from those disclosed in the cited prior art by definition. Applicant submits that no one having knowledge or skill in the art and science of homeopathy would confuse a pharmaceutical preparation with a homeopathic preparation or view them as the same or similar or equivalent – or view a homeopathic potency of a homeopathic preparation as obvious in view of a pharmaceutically prepared composition.

Homeopathic preparations are characterized and defined by the composition (not concentration) of the starting material and their method of preparation – *not* by the molar concentration of the preparation, and *not* by the molar concentration of the starting material. *Antoniades et al.* do ***not*** disclose or suggest the use of applicants' claimed preparations comprising a homeopathic potency of purified IGF-1 as specified in applicant's claims. Applicant requests withdrawal of the outstanding rejection under 102(b) or final rejection of applicant's claims so that this issue may proceed to appeal.

**Claim Rejections under 35 USC §112, first paragraph**

Claims 1, 2, 11, 13-28 and 30-33 are rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement which was maintained for reasons set forth in a previous Office action. Applicant traverses this rejection for the reasons set forth in Applicant's responses to the same rejection stated in the previous Office action. Applicant awaits a final rejection so these issues may be resolved on appeal.

The test for enablement, as noted by the Examiner, is whether undue experimentation is necessary to teach *one skilled in the art* to make and/or use the invention. The Examiner states that in the absence of a starting concentration of IGF-1, there is insufficient guidance provided for making and/or using the claimed homeopathic preparations. The Examiner states, additionally, that the starting (molar) concentration of IGF-1 is required to obtain the various homeopathic potencies. The Examiner furthermore states that homeopathic potencies of IGF-1 suitable for oral administration may not have any clinical effect as a consequence of the biological stability, half-life or clearance of the preparation from the blood. The Examiner states that there is no teaching in the specification with respect to the various pathologies associated with the various physiological disorders relating to IGF-1 caused by various etiologies and there are no working examples describing the treatment of various physiological disorders by administering homeopathic preparations of IGF-1.

The Examiner is treating the claimed preparations as allopathically prepared (i.e. traditional) pharmaceutical preparations. They are not. The preparation of homeopathic

potencies is straightforward and has been practiced for hundreds of years. Evidence describing the preparation and use of homeopathic preparations has been submitted previously in this prosecution. Applicant included in a response to a previous Office Action, an excerpt from the Homeopathic Pharmacopoeia (Revision Service) of the United States that described how homeopathic preparations are prepared. For additional general information relating to homeopathy and the Homeopathic Pharmacopoeia of the United States, the Examiner is invited to review information provided on the Website www.hpus.com.

The Homeopathic Pharmacopeia of the United States has been in continuous publication since 1897 and governs homeopathic products sold in the U.S. It provides a straightforward explanation of the preparation of homeopathic potencies. There is no reference to molar concentrations of starting material and, as pointed out above, the molar concentration is not relevant to the homeopathic potency. This is very difficult for traditionally trained scientists to understand, but this is the art and science of homeopathy, and these principles and methods for making homeopathic preparations are well known and well accepted within the community of homeopathy. Applicant's specification and the knowledge in the art provide sufficient guidance to one of ordinary skill in the art to make the claimed preparations.

The use of homeopathic preparations is also well known. As noted on the Website of the Homeopathic Pharmacopoeia of the United States, homeopathy has historically been practiced by medical doctors, and has been used for self-care by the general public. As further noted on the HPUS Website (www.hpus.com):

> Homeopathy is an ideal therapeutic medium for self-medication of symptoms usually associated with self-limiting conditions since the selection of the proper remedy for the case is dependent on the symptoms that the body exhibits in its reaction to the illness.

Substantial commercial sales of preparations comprising homeopathic potencies of purified IGF-1 have taken place in the past several years. The use of homeopathic preparations does not require clinical testing or proof of efficacy or knowledge of the mechanism associated with physiological effects. Consumer users are well skilled in the art of using homeopathic preparations and homeopathic practitioners are well skilled in the art of prescribing homeopathic

preparations. Their use is not governed by pathologies or by mechanisms of action but, rather, by the effect(s) it produces. The use of the claimed preparations is well within the skill of both homeopathic practitioners and consumer users.

The Examiner continues to apply an allopathic analysis to applicant's claims and the requirements of 35 U.S.C. 112. The test for enablement, as noted by the Examiner, is whether undue experimentation is necessary to teach *one skilled in the art* to make and/or use the invention. The Examiner has not considered this requirement in light of what one skilled in the art *of homeopathy* would know or require. Applicant submits that the pending claims are enabled in the manner required by 35 U.S.C. 112. Those having knowledge of and familiarity with the art and science of homeopathy would be able to both make and use the claimed compositions comprising homeopathic potencies without undue experimentation. Applicant requests withdrawal of the outstanding rejection under 112 or final rejection of applicant's claims so that this issue may proceed to appeal.

**Double Patenting**

Claims 1, 2, 11, 13-28 and 30-33 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-14, 16 and 19 of U.S. Patent No. 6,239,105. This rejection is traversed.

The '105 patent claims are directed to compositions comprising a homoeopathic preparation of purified growth hormone. The Examiner states that the pending claims are fully disclosed in the '105 patent claims. Applicant fails to see how claims to homeopathic potencies of purified IFG-1 are fully disclosed in claims to homeopathic preparations of purified growth hormone.

Claims 1, 2, 11-28 and 30-33 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-20 of co-pending U.S. Application No. 11/242,988. This rejection is traversed. The '988 application has been abandoned.

## Concluding Remarks

It is submitted that pending claims 1, 2, 11, 13-28 and 30-33 are all in allowable form and early allowance is respectfully solicited. Should the Examiner have any concerns regarding the subject patent application, she is respectfully invited to telephone the undersigned at 206.382.1191.

Respectfully submitted,

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